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Christopher Burgess

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EXAMINER

LONG, SCOTT

ART UNIT

PAPER NUMBER

1633

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DELIVERY MODE

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PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/700,439

Applicant(s)

BURGESS ET AL.

Examiner

Scott D. Long

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1633

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 August 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-33 is/are pending in the application.
- 4a) Of the above claim(s) 1-5, 8-33 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 6 and 7 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

The examiner acknowledges receipt of Claim Amendments and Applicant's Remarks, filed 14 August 2007.

Claim Status

Claims 1-33 are pending. However, claims 1-5 and 8-33 are withdrawn from further consideration by the Examiner, pursuant to 37 CFR 1.142(b), as being drawn to non-elected inventions, there being no allowable generic or linking claim. Claim 6 is amended. Claims 6-7 are under current examination.

Priority

The instant application has been granted the benefit date, 11 April 2003, from the filing date of the instant application.

Response to Arguments - Claim Rejections 35 USC § 112

*Response to Arguments – SCOPE OF ENABLEMENT
(35 USC 112, first paragraph)*

Applicant's claim amendments and arguments (Remarks, pages 11-12) filed 14 August 2007 have been fully considered and they are persuasive.

The applicant has amended the scope of the claims to methods of detecting colon cancer and further pointed out that Example 1 is directed to identification of differentially expressed marker sequences in colon (page 76).

Therefore, the rejection of claims 6-7 under 35 USC 112, first paragraph is hereby withdrawn.

Response to Arguments - Claim Rejections 35 USC § 102

Applicant's claim amendments and arguments (Remarks, page 12) filed 14 August 2007 have been fully considered, and they are persuasive.

Therefore, the rejection of claims 6-7 under 35 USC 102(e) as anticipated by Su et al. is hereby withdrawn.

Response to Arguments - Claim Rejections Double Patenting

Applicant's claim amendments and arguments (Remarks, page 13) filed 14 August 2007 have been fully considered, and they are persuasive.

The examiner thanks the applicant for pointing out that applications 09/879536 and 09/871161 are abandoned. Therefore, the ODP rejections over these applications are moot and hereby withdrawn.

Therefore, the provisional ODP rejections of claims 6-7 as conflicting with claims in applications 09/879536 and 09/871161 are hereby withdrawn.

As application No. 09/328111 is now an issued patent and does not include claims that conflict with Claims 6-7 of the instant application, the examiner hereby withdraws the provisional ODP rejection.

As amended, claims 6-7 no longer encompasses the same breadth as claim 1-2 of copending Application No. 10/610049. Since the claims are no longer in conflict, the examiner hereby withdraws the provisional ODP rejection.

NEW GROUNDS OF REJECTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 6-7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Su et al (US application - US20040005644A1) in view Chan et al. (US application - US2007/0010469).

Claim 6 is directed to a method of detecting colon cancer or a pre-malignant condition thereof in a subject comprising comparing a) the expression level of a nucleic acid comprising the sequence of SEQ ID NO:1 in a biological sample from the subject with b) a control expression level of said nucleic acid sequence, wherein a change of at

least two-fold in the expression level of said nucleic acid sequence is indicative of cancer or a pre-malignant condition thereof. Claim 7 is directed to the method of claim 6, wherein said change in the expression level is either an increase or decrease in the expression level.

Su et al. teach, "method for detecting breast cancer in a subject, said method comprising the steps of: (a) determining a level of a transcribed polynucleotide in a biological sample from said subject, wherein said transcribed polynucleotide comprises a nucleic acid sequence recited in any one of SEQ ID NOS:1-19, or a complement of any of the foregoing nucleic acid sequences; (b) comparing the level of said transcribed polynucleotide in said biological sample to a control level of said transcribed polynucleotide; and (c) producing a diagnosis based on a result from step (b)." (claim 6, page 87). Su et al. further teach "the term 'breast cancer specific gene (BCSG)' refers to a gene that is over-expressed by at least two-fold (i.e. 200% of normal) or under-expressed by at least two-fold (i.e. 200% of normal) in breast cancer tissue or cell lines relative to normal tissue or cell lines." (page 3, paragraph 0026) Su et al. also teach SEQ ID NO:6 which is a 2163 bp polynucleotide sequence that is 100% identical to SEQ ID NO:1 of the instant application. Su et al. also teach, "The invention also includes an array comprising a panel of BCSMs of the present invention. The array can be used to assay expression of one or more genes in the array....The array may be hybridized with for example, polynucleotides extracted from a blood or colon sample from a subject....thus the presence or quantity of the BCSG and BCSG transcripts in the sample can be ascertained." (page 25, parag.0126-0127). Su et al. also teaches

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that various of the overexpressed genes are known to be involved in human cancers, including KRT23 (SEQ ID NO:6 of Su; SEQ ID NO:1 of application 10/700439). (page 17, parag.0051).

Su et al. teaches all the limitations of instant claims. The method steps of the instant claims are taught by Su et al. and the particular gene assayed (SEQ ID NO:1) is also taught by Su et al. and furthermore Su et al. suggest using the method on nucleic acids isolated from colon tissue. However, Su et al. does not specifically state that their method can be used as a method of detecting colon cancer.

Chan et al. teach, "The present invention provides polynucleotides, as well as polypeptides encoded thereby, that are differentially expressed in cancer cells. These polynucleotides re useful in a variety of diagnostic and therapeutic methods." (abstract). Chan et al. further teach, KTR23 (Table 3, page 42, SEQ ID NO:164) (same as SEQ ID NO:1 of instant application) as one of the polynucleotides differentially expressed in cancer cells, including...colon (page 3, parag.0044).

It would have been obvious to the person of ordinary skill in the art at the time of the invention was made to utilize a nucleic acid encoding KTR23 in a method for detecting colon cancer using differential expression profiling.

The person of ordinary skill in the art would have been motivated to substitute one known, equivalent element for another to obtain predictable results. The claimed method would have been obvious because the substitution of one known element for another would have yielded predictable results to one of ordinary skill in the art at the time of the invention. In the instant case, it would have been obvious to substitute a

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polynucleotide comprising the gene for KRT23 (also known as SEQ ID NO:1 in the instant application) in a method for detecting colon cancer because Chan et al. teach the link between KRT23 and Colon cancer, while Su et al. provide a method for detecting differential expression of KRT23 in breast cancer and also suggest using nucleic acids isolated from colon cells in their method.

Therefore the method as taught by Su et al. in view of Chan et al. would have been *prima facie* obvious over the method of the instant application.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

No claims are allowed.

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Examiner Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Scott Long** whose telephone number is **571-272-9048**.

The examiner can normally be reached on Monday - Friday, 9am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph Woitach** can be reached on **571-272-0739**. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Art Unit 1633

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JLE